

King, Valerie A.

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**From:** Gogova, Maria  
**Sent:** Friday, October 24, 2003 1:30 PM  
**To:** King, Valerie A.  
**Subject:** RE: As requested

DSS:

Valerie,

Just quick follow up. Since me and Paul are taking part in EHCS teleconference, I was aware of Mike's plans. He presented those dates at last Fri teleconference. According to Mike, those dates came up at last DRB meeting. Paul showed strong disagreement on planning clinical study conduct without involving CE members. Mike agreed and told us, that this timeframe was presented by somebody whose name I forgot.. (it was not Mike). The other thing is, it is not final and dates depend on currently running non-clinical studies, which should give a "go" for clinical study conduct. The results of those studies should be available by the end of this year. But as you know, I was not here, things could have changed, and Paul might have already updated you.

Below find the "scenario" sheet presented at DRB.  
Please if you have any questions just let me know.

Maria



DRB 10\_16\_03  
Scenario Planning...

-----Original Message-----

**From:** King, Valerie A.  
**Sent:** Wednesday, October 22, 2003 5:37 PM  
**To:** Gogova, Maria  
**Subject:** FW: As requested

Hi Maria:

If you don't mind, take a look at the issue log document (see below) as it relates to K6 Domestic Long Term clinical study comments. Mike has added language that suggests that the date for the long term study has been set in March '04. I don't think this is confirmed, but I wasn't sure if subsequent decisions had been made that haven't yet been communicated to us or MDS. We've been expecting a study no sooner than March 04. Can you confirm? I know you're in Phoenix until Friday, so I'll just address revisions (if needed) in the next addition of our input to the issue log.

Thanks and hope you had a good trip!

-Valerie

-----Original Message-----

**From:** Schuster, Dave  
**Sent:** Wednesday, October 22, 2003 12:59 PM  
**To:** Nixon, Gerry M.; Gaworski, Charles L.; King, Valerie A.  
**Subject:** FW: As requested

Mike's input

-----Original Message-----

**From:** Werley, Michael S  
**Sent:** Wednesday, October 22, 2003 11:18 AM

**To:** Schuster, Dave  
**Subject:** As requested

<< File: Summary Product Testing 09-29-03-with Revisions for Dave.doc >> << File: WSA Issue Log 10-02-03-with revisions for Dave.xls >>